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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/04/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/606,314</b>	Applicant(s) <b>Fike et al.</b>
Examiner <b>Michele Flood</b>	Art Unit <b>1651</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Mar 19, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 27, 29-37, 39-55, 60-72, and 92-99 is/are pending in the application.

4a) Of the above, claim(s) 29-35, 40-43, 48-55, 60-69, 71, and 96-99 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 27, 36, 37, 39, 44-47, 70, 72, and 92-95 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group I, Claims 27, 36, 37, 39, 44-47, 70, 72 and 92-95 in Paper No. 13 is acknowledged. The traversal is on the ground that there is no undue burden for the examiner to search and examine both Groups I and II. This is not found persuasive because the invention of Group I is directed to a nutritive medium powder prepared by agglomerating a dry powder eukaryotic nutritive medium with a solvent, whereas the invention of Group II is directed to a nutritive medium powder prepared by spray-drying a liquid medium powder, then agglomerating the powder with a solvent. The product of Group I does not require a step of spray-drying, whereas the product of Group II does require a step of spray-drying.

Furthermore, the inventions of Group I and II are separate and distinct as they require materially different searches; a search of the art for one product would not necessarily encompass all of the products. Additional search terms would be required for a thorough search of the claimed products, thus resulting in a larger more burdensome search for the examiner.

The requirement is still deemed proper and is therefore made FINAL.

**Claims 27, 36, 37, 39, 44-47, 70, 72 and 92-95 are under examination.**

The claims have been examined, insofar, as they read on the elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 36, 70, 72 and 92-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 27 are rendered uncertain by the term "eukaryotic nutritive medium powder" because it is unclear as to whether the invention is directed to a nutritive medium powder consisting of dried eukaryotic cells or to a nutritive medium powder for the culturing or growth of eukaryotic cells.

Claim 36 recites the limitation "nutritive medium powder" in line 1. The claim lacks clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by placing eukaryotic .

The metes and bounds of Claim 36 are rendered uncertain by the phrase "wherein said nutritive medium has a pH of between 7.1 and 7.5 when said medium is reconstituted with a solvent" because it is uncertain as to which solvent would provide the claimed designated pH value when used for the purpose of reconstitution. Since it is unclear as to what is the pH value of the end product, it is also unclear as to what particular solvent Applicant intends to use for providing the claimed designated product by process. The lack of clarity makes the claim

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ambiguous. Moreover, the phrase is directed to an after process limitation that provides for a product which is outside the scope of the claimed invention.

Claim 95, line 1, recites the limitation "any one of the claims 93-95" which renders the claim indefinite because a claim cannot depend upon itself.

Claim 95 recites the limitation "wherein the medium powder that is not agglomerated" in lines 1-2. The claim lacks clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing the limitation with wherein the non-agglomerated medium powder.

All other claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 36, 37, 39 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisecky et al. (AC1).

Applicant claims a eukaryotic nutritive medium powder prepared by agglomerating a dry powder eukaryotic nutritive medium with a solvent. Applicant further claims the nutritive

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medium powder of any of claims 27-31, wherein said nutritive medium powder has a pH of between 7.1 when said medium is reconstituted with a solvent. Applicant further claims a nutritive medium supplement powder prepared by agglomerating a dry nutritive medium with a solvent. Applicant further claims a nutritive medium subgroup powder prepared by agglomerating a dry powder nutritive medium subgroup with a solvent. Applicant further claims the nutritive medium supplement powder of claim 37, wherein said nutritive medium supplement comprises one or more nutritive medium components.

Pisecky teaches a process of making an agglomerated powdery milk product, which is fit for food and fodder consumption. Liquid milk or whey is sprayed into a stream of drying gas (air) at 200°-400°C to form agglomerated powder particles, which are further dried. Given the broadest breadth of interpretation of the claims, the agglomerated powdery milk product powders taught by Pisecky are read as “a nutritive medium powder”, “a nutritive medium supplement powder”, and “a nutritive medium subgroup powder” because the referenced products can be used in the culturing of animal cells (as evidenced by the teachings of Pisecky) and can be grouped within the scope of the various media subgroupings as described by Applicant on page 6, lines 13-28 and page 7, wherein dried milk can be considered as an animal extract of mammalian cells containing fats, proteins and vitamins, etc.

Please note that “The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was

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made by a different process.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

The reference anticipates the claimed subject matter.

Claims 27, 36, 37, 39, 47 and 92-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Peebles (A) and Getler et al. (N), as evidenced by the teachings of Hup et al. (B).

Applicant’s claimed invention of Claims 27, 36, 37, 39 and 47 was set forth above. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium powder of any of claims 93-95, wherein the medium powder that is not agglomerated is a lyophilized or ball-milled powder.

Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. See Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting. See claims and Column 9, lines 46-54.

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Getler teaches agglomerated milk products and milk-like products which are made in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (see page 1, lines 11-14); and a fat component mixed with water, vitamins, and with raw materials in powder form, i.e., casein, whey, skim milk, malto dextrine, etc. (see page 6, line 36 to page 7, lines 1-2). In Example 3, Getler teaches an agglomerated nutritive medium powder which exhibits reduced dusting and rapid dissolution.

Given the broadest breadth of interpretation of the claims, the agglomerated powders taught by Peebles and Getler are read as “a nutritive medium powder”, “a nutritive medium supplement powder”, and “a nutritive medium subgroup powder” because the products can be used in the culturing of cells (as evidenced by the teachings of Hups) and can be grouped within the scope of the various media subgroupings as described by Applicant on page 6, lines 13-28 and page 7, wherein dried milk can be considered as an animal extract of mammalian cells containing fats, proteins and vitamins, etc., and whey protein concentrates can be considered as a plant cell.

The references anticipate the claimed subject matter.

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Claims 37, 39 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Robey et al. (AS4) and Camire et al. (AR4).

Applicant claims a nutritive medium subgroup powder prepared by agglomerating a dry powder nutritive medium subgroup with a solvent. Applicant further claims the nutritive medium subgroup powder of claim 37, wherein said nutritive medium supplement powder is serum; wherein said serum is bovine or human serum; and wherein said bovine serum is fetal bovine serum or calf serum.

Robey and Camire each teach a powdered fetal bovine serum.

Please note that “The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

The references anticipate the claimed subject matter.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 36, 37, 39, 44-47, 70, 72 and 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peebles (A), Getler et al. (N), Robey et al. (AS4) and Camire et al. (AR4) in view of DiSorbo et al. (AG2).

Applicant's claimed invention of Claims 27, 36, 37, 39, 44-47 and 92-95 was set forth above. Applicant further claims a kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains the powder of an one of claims 27, 29-31, 37, 39-43 and 60. Applicant further claims a kit of claim 70, further comprising one or more additional containers containing one or more solvents.

The teachings of Peebles, Getler, Robey and Camire are set forth above. Peebles, Getler, Robey and Camire teach the claimed invention except for a kit. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the powders taught by Peebles, Getler, Robey and Camire in the making of a kit by containing the referenced powders in a first container and providing one or more additional containers containing one or more solvents because DiSorbo teaches a kit comprising one or more

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containers containing nutritive media, media supplements and media subgroups and one or more containers containing solvents, which can be used to formulate a medium to support the in vitro cultivation of a cell, e.g., bacterial cell, a fungal cell, a plant cell, or an animal cell. One of ordinary skill in the art would have been motivated to combine the instantly claimed materials in the making of a kit for use in the cultivation of a cell because one would have had a reasonable expectation of success that the making of the claimed kit as a product of sale would be useful and convenient to the biomedical community because DiSorbo relates the reduced cost that his invention provides for the preparation of cell culture media, since the media subgroupings can be easily stored and admixed to make custom media, when needed.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

MCF

May 30, 2002



CHRISTOPHER R. TATE  
PRIMARY EXAMINER